



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. FDA-2009-P-0147]

Flavored Milk; Petition to Amend the Standard of Identity for Milk and 17 Additional Dairy Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments, data, and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) have filed a petition requesting that the Agency amend the standard of identity for milk and 17 other dairy products to provide for the use of any safe and suitable sweetener as an optional ingredient.

FDA is issuing this notice to request comments, data, and information about the issues presented in the petition.

DATES: Submit either written or electronic comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2009-P-0147 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

### Written Submissions

Submit written submissions in the following ways:

Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

### FOR FURTHER INFORMATION CONTACT:

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### SUPPLEMENTARY INFORMATION:

#### I. IDFA and NMPF Petition

The IDFA and NMPF jointly submitted a citizen petition (Ref. 1) on March 16, 2009, requesting that FDA amend the standard of identity in part 131 (21 CFR 131) for milk (§ 131.110). Specifically, the petition requests that FDA amend § 131.110(c)(2) to allow the use of “any safe and suitable” sweetener in optional characterizing flavoring ingredients used in milk.<sup>1</sup> The petition also requests that FDA similarly amend the standards of identity for 17 other milk and cream products. Those standards (hereinafter referred to as the “additional dairy standards”) are as follows: Acidified milk (§ 131.111), cultured milk (§ 131.112), sweetened condensed milk (§ 131.120), nonfat dry milk (§ 131.125), nonfat dry milk fortified with vitamins A and D (§ 131.127), evaporated milk (§ 131.130), dry cream (§ 131.149), heavy cream (§ 131.150), light cream (§ 131.155), light whipping cream (§ 131.157), sour cream (§ 131.160), acidified sour cream (§ 131.162), eggnog (§ 131.170), half-and-half (§ 131.180), yogurt (§ 131.200), lowfat yogurt (§ 131.203), and nonfat yogurt (§ 131.206). The petition asks that the standards of identity for these products be amended to provide for the use of any safe and suitable sweetener in the optional ingredients.<sup>2</sup>

IDFA and NMPF request their proposed amendments to the milk standard of identity to allow optional characterizing flavoring ingredients used in milk (e.g., chocolate flavoring added to milk) to be sweetened with any safe and suitable sweetener—including non-nutritive sweeteners such as aspartame. IDFA and NMPF state that the proposed amendments would

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<sup>1</sup> Section 131.110(c)(2) currently allows the use of “nutritive sweetener” in optional characterizing flavoring ingredients used in milk.

<sup>2</sup> The National Yogurt Association (NYA) submitted a citizen petition on February 18, 2000 (Docket No. FDA-2000-P-0126) that requested that FDA make similar changes to the standards of identity for yogurt and cultured milk. Among other requested changes, the NYA petition asked that FDA amend the standards of identity for yogurt and cultured milk to permit the use of all safe and suitable sweeteners, while also revoking the standards of identity for lowfat and nonfat yogurt. In 2009, FDA proposed to grant the petition in part, and to deny it in part. See “Milk and Cream Products and Yogurt Products; Proposal to Revoke the Standards for Lowfat and Nonfat Yogurt and to Amend the Standard for Yogurt” (74 FR 2443, January 15, 2009). Thus, FDA has already requested comments on issues that are similar to the issues IDFA and NMPF raise with respect to yogurt, lowfat yogurt, nonfat yogurt, and cultured milk, and is addressing those issues through the rulemaking initiated in response to NYA’s petition. Therefore, FDA is not currently requesting comments on IDFA and NMPF’s suggested amendments to the yogurt, lowfat yogurt, nonfat yogurt, and cultured milk standards.

promote more healthful eating practices and reduce childhood obesity by providing for lower-calorie flavored milk products. They state that lower-calorie flavored milk would particularly benefit school children who, according to IDFA and NMPF, are more inclined to drink flavored milk than unflavored milk at school. As further support for the petition, IDFA and NMPF state that the proposed amendments would assist in meeting several initiatives aimed at improving the nutrition and health profile of food served in the nation's schools. Those initiatives include state-level programs designed to limit the quantity of sugar served to children during the school day. Finally, IDFA and NMPF argue that the proposed amendments to the milk standard of identity would promote honesty and fair dealing in the marketplace and are therefore appropriate under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

The petition acknowledges that the use of non-nutritive sweeteners in optional characterizing flavoring ingredients in milk is allowed under the existing regulatory scheme, with certain additional requirements. The regulatory framework governing the naming of standardized foods that do not fully comply with the relevant standards of identity changed with the passage of the Nutrition Labeling and Education Act of 1990 and FDA's rulemaking establishing the Agency's requirements for foods named by use of a nutrient content claim and a standardized term (§ 130.10 (21 CFR 130.10)). Section 130.10(d) allows the addition of safe and suitable ingredients to a food named by use of a nutrient content claim and a standardized term when these ingredients are used to, among other things, add sweetness to ensure that the modified food is not inferior in performance characteristic to the standardized food even if such ingredients are not specifically provided for by the relevant food standard. Therefore, while the milk standard of identity in § 131.110 only provides for the use of "nutritive sweetener" in an optional characterizing flavor, milk may contain a characterizing flavor that is sweetened with a

non-nutritive sweetener if the food's label bears a nutrient content claim (e.g., "reduced calorie") and the non-nutritive sweetener is used to add sweetness to the product so that it is not inferior in its sweetness property compared to its standardized counterpart. However, IDFA and NMPF argue that nutrient content claims such as "reduced calorie" are not attractive to children, and maintain that consumers can more easily identify the overall nutritional value of milk products that are flavored with non-nutritive sweeteners if the labels do not include such claims. Further, the petitioners assert that consumers do not recognize milk--including flavored milk--as necessarily containing sugar. Accordingly, the petitioners state that milk flavored with non-nutritive sweeteners should be labeled as milk without further claims so that consumers can "more easily identify its overall nutritional value."

As to the additional dairy standards, IDFA and NMPF state that administrative efficiency counsels in favor of similar changes. As long as FDA is dedicating resources to amending the standard of identity for milk, they argue, the Agency should also amend the standards for these products at the same time. They state that it is most efficient to consider all of the proposals together. According to the petition, the requested changes to the additional dairy standards present the same issues as the milk standard, and it is therefore appropriate to consider all of the requested changes together.

## II. Request for Comments

FDA requests that interested persons submit comments, data, and information concerning the need for, and the appropriateness of, amending the standard of identity for milk and the additional dairy standards. FDA specifically requests comment and supporting data, as appropriate, on the following matters:

1. The petition states that amending the standard of identity for milk (§ 131.100) to allow the use of “any safe and suitable” sweetener in optional characterizing flavoring ingredients would promote honesty and fair dealing in the interest of consumers by creating consistency in the naming of flavored milk products because flavored milk could contain a non-nutritive sweetener without bearing a nutrient content claim (e.g., “reduced sugar”) as part of its name. Would the proposed amendments promote honesty and fair dealing in the interest of consumers?

2. If the standard of identity for milk is amended as requested by petitioners, milk manufacturers could use non-nutritive sweeteners in flavored milk without a nutrient content claim in its labeling. Will the inclusion of the non-nutritive sweeteners in the ingredient statement provide consumers with sufficient information to ensure that consumers are not misled regarding the characteristics of the milk they are purchasing?

3. The petition states that flavored milk labels that bear nutrient content claims such as “reduced calorie” are unattractive to children. What, if any, data are available on children’s purchase habits with regard to flavored milks labeled as “reduced calorie flavored milk,” “no sugar added,” “less sugar,” etc?

4. The petition states that if FDA dedicates resources to amending the standard of identity for milk, for purposes of administrative efficiency the Agency should also amend the Additional Dairy Standards because the issues presented are the same with respect to the use of non-nutritive sweeteners. Would amending the Additional Dairy Standards as requested promote honesty and fair dealing in the interest of consumers? If the labels of these products do not bear nutrient content claims, would the inclusion of non-nutritive sweeteners in the ingredient statements provide consumers with sufficient information to distinguish between the two types of

products (i.e., sweetened with nutritive versus non-nutritive sweeteners) so that consumers are not misled?<sup>3</sup>

5. The petition notes that ice cream is permitted to contain either a nutritive or non-nutritive sweetener without the label bearing a nutrient content claim or otherwise distinguishing the two types of products from one another. Are the considerations underlying FDA amendments to the standard of identity for ice cream<sup>4</sup> applicable to the requested amendments to the standard of identity for milk or the Additional Dairy Standards?

6. If the standard of identity for milk and the Additional Dairy Standards are amended in the manner requested by the petition, what will be the effect on search costs<sup>5</sup> for consumers who would like to determine whether a product contains a nutritive or non-nutritive sweetener?

After reviewing the comments received, FDA will further evaluate the need for, and appropriateness of, the amendments requested by IDFA and NMPF and will decide what further actions are appropriate. For a copy of the petition filed by IDFA and NMPF please go to:

<http://www.regulations.gov> and insert “Docket No. FDA-2009-P-0147” into the “Search” box.

(Authority: 21 U.S.C. 321 et seq.)

### III. References

FDA has placed the following references on display. To view the references, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of

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<sup>3</sup> Although FDA requests comments relevant to the IDFA and NMPF petition, FDA does not seek comments regarding the requested amendments to the standards of identity for yogurt, lowfat yogurt, nonfat yogurt, and cultured milk. FDA has already sought and collected comments regarding similar amendments to those standards in a proposed rulemaking. See 74 FR 2443.

<sup>4</sup> FDA amended the standard of identity for ice cream to allow for “any safe and suitable sweetener” to be used in ice cream. See “Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat’s Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat’s Milk Ice Cream” (59 FR 47072, September 14, 1994) (Ref 2). Before FDA’s amendment, the standard provided only for “nutritive carbohydrate sweeteners.”

<sup>5</sup> Search costs include the time and energy it would take an average consumer to read a label and determine whether the product contained the nutritive sweetener or the artificial sweetener.

this document, into the “Search” box. The references may also be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

1. International Dairy Foods Association and the National Milk Producers Federation, Citizen Petition, March 16, 2009.

2. “Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat’s Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat’s Milk Ice Cream” (59 FR 47072, September 14, 1994).

Dated: February 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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